More Oversight of Drug Trials Urged

Overseas Testings Pose 'a Serious Problem,' Study Says

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The Food and Drug Administration has few details about the dramatic rise in overseas drug testing and reforms are needed to protect both foreign patients taking experimental medicines and Americans who buy products based on their results, a federal audit concludes.

The number of pharmaceutical researchers working outside the United States who voluntarily report their experiments to the FDA increased 16-fold from 1990 to 1999, dwarfing the agency's ability to inspect the test sites, according to the report set for release today by the inspector general's office at the U.S. Department of Health and Human Services. More worrisome, the report said, is that the FDA does not know how many such tests are not reported.

"It's a serious problem, it's growing, there needs to be something done about it right away," George Grob, a deputy HHS inspector general, said yesterday. "FDA's control is inherently weak and it is a problem that is inherently dangerous."

Grob said the study underscores findings in a Washington Post investigation published in December, which charted how U.S. drug companies increasingly export medical experiments to the Third World, where patients are plentiful and government oversight is lax.

In recent weeks, the FDA has opened a criminal investigation into irregularities in a Nigerian drug trial sponsored by Pfizer Inc., and the families of 30 children who participated in the study have filed suit against Pfizer in New York. Legislation is pending that would strengthen federal oversight of foreign trials, and HHS has created an office to oversee federally funded overseas experiments.

The audit says foreign drug trials have skyrocketed in Eastern Europe and Latin America and in Russia, where ethics review boards often are inexperienced and unsure of their roles.

The FDA is unable to ensure that trial participants in those countries receive the same level of protection as those in the United States, the report found. Regulators in Third World nations cannot be relied upon to make sure patients are fully informed of risks and sign up willingly, it said.

"Our review represents a significant warning signal" that the FDA cannot guarantee those participants are protected adequately in a growing proportion of research, the report said.

Among experiments voluntarily reported to the FDA, the study said, the number of overseas researchers leapt from 271 in 1990 to more than 4,400 in 1999. A decade ago, the FDA inspected more than 8 percent of such operations. By 1999, the portion inspected had fallen to just more than 1 percent.

The FDA has little idea where research takes place overseas, what level of ethics review exists, how foreign researchers recruit participants or how many patients are taking experimental medicines, the study said.

The report recommends that the FDA help train overseas ethics boards, which must pre-approve trials, and collect more information about how they operate. It also says the agency should push foreign researchers to sign pledges that they will adhere to FDA rules and should encourage U.S. companies to more closely monitor overseas tests.

The Human Research Protections Office, a separate division of HHS, also should work to guarantee the protection of foreign research subjects, the study said. And the office should push for a voluntary accreditation program for foreign ethics boards.